PATENT

In re Application of: Tamburini et al.

Application No.: 09/974,026 Filed: October 10, 2001

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Attorney Docket No.: AERO1130-4

REMARKS

A. Regarding the Amendments

Claims 12-17 are pending. Claims 12-17 have been amended to correct typographical errors and other minor informalities, as suggested by the Examiner. Several paragraphs of the specification have been also amended to correct typographical errors and other minor informalities as suggested by the Examiner.

In particular, in claim 13, the limitation "SEQ ID NO:9, 32, 44, 46, 48, 51, and 75" has been replaced with the limitation "SEQ ID NOS: 9, 32, 44, 46, 48, 51 or 75," to show that there is a plurality of sequences. In each of claims 15 and 17, the limitation "is" has been moved after the identifier "(a)" to properly conjugate the subject "protein" with the verb "contains." In claim 16, the word "preparing" has been replaced by "producing."

With regard to the abbreviations "PCR" and "SDS-PAGE" it is submitted that these are common terms known to those having ordinary skill in the art. As required by the Examiner, the abbreviation "PCR" has been spelled out where it first appears in the specification (page 13, line 13) to clarify that it means "polymerase chain reaction" throughout the application. The abbreviation "SDS-PAGE" has been spelled out where it first appears in the specification (page 14, line 26) to clarify that it means "sodium dodecyl sulfate-polyacrylamide gel electrophoresis" throughout the application.

With regard to the abstract, the Applicants respectfully point out that the abstract has been added to the specification by the preliminary amendment filed on March 12, 2002. Here, the Applicants put the abstract on a separate page as required by MPEP Section 608.01(b).

Accordingly, it is submitted that the amendments to specification and claims do not introduce any new matter.

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B. Rejection Under 35 USC § 112, First Paragraph (Written Description).

Claims 12-17 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The burden of demonstrating that the claims are allegedly not supported by an adequate written description is squarely on the Examiner, as required by *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). MPEP specifically states that a strong presumption of adequacy of written description exists and directs that § 112, paragraph 1 rejections of an original claim should be rare. MPEP §§ 2163(I)(A) and 2163(II)(A). It is respectfully submitted that in this case the Examiner has not met this burden.

The legal standard for determining the adequacy of written description is clear and well established. The description is adequate if "the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at [the time of filing] of the later claimed subject matter." Wang Labs Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767. In other words, the question of the lack of adequate written description does not arise unless "one skilled in the art [would not be able] to immediately envisage the product claimed..." Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895. It is submitted that applying these broad principles to the present application, it can be unequivocally concluded that the written description in this application adequately supports the claims.

More particularly, the Examiner has asserted (page 4, second paragraph of the Office Action) that the Applicants were not in possession of the nucleic acid sequences SEQ ID NOS: 5, 6, and 8, thus making the description defective. The Applicants respectfully disagree. The Applicants point out that by the preliminary amendment filed on March 12, 2002, the instant

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application added the claim of priority to U.S. Serial Number 09/144,428 filed August 31, 1998 (now issued as U.S. Patent No. 6,583,108). Claim 2 of the '108 patent recites:

"A ... purified ... protein containing at least one Kunitz-like domain comprising an amino acid sequence ... SEQ ID NO: 8..."

Claim 3 of the '108 patent similarly claims a protein having SEQ ID NOS: 5 and 6. Since claims directed to proteins containing the sequences SEQ ID NOS: 5, 6, and 8 were allowed by the USPTO, this serves as *prima facie* evidence of the fact that the Applicants were indeed in possession of these sequences. Clearly, if the Applicants were in possession of the sequences when they claimed the protein, they must necessarily be in possession of the same sequences when they claim an isolated nucleic acid which encodes such protein, as claimed in claim 12.

In view of the foregoing, the present specification contains a complete description of the invention sufficient to demonstrate that the Applicants, at the time the application was filed, had possession of the claimed invention. Accordingly, it is respectfully submitted that the rejection of claims 12-17 under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description, is not properly applied. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

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CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved. No fee is believed due in connection with this Response. However, The Commissioner is hereby authorized to charge any fees that may be associated with this communication, or credit any overpayment to Deposit Account No. 50-1355.

Respectfully submitted,

Date: October 1, 2004

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